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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,452	02/17/2004	Janel E. Young	ETH5123 [14758]	1524

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ROBERT'S MLOTKOWSKI SAFRAN & COLE, P.C.

Intellectual Property Department

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1617

NOTIFICATION DATE

DELIVERY MODE

04/11/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/780,452

Applicant(s)

YOUNG ET AL

Examiner

Carlos A. Azpuru

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17-19, 21-24, 27, 28, 31, 34-37 and 39-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 14, 17-19, 21-24, 27, 28, 31, 34-37 and 39-41 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the remarks filed 04/15/2010. A status inquiry was also filed on 12/30/2010. For future reference, applicant is notified that status inquiries are never brought to the examiner's attention. A phone call to the examiner might work better to get a case moving if it has someone been lost in the system.

The following rejections are maintained in this action:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 17-19, 21-24, 27, 28, 31, 34-37, 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-19, 21-24, 27-31, 34 of copending Application No. 12/021,546 (US'546). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'546 claims a composition and drug delivery vehicle for inhibiting adhesions (claim 1) using delivery vehicles (claims 3 and 15) of Pemirolast (claim 2). Therapeutic agents are set out in claim 6, Dosage of Pemirolast is found in claim 11. The vehicle may comprise a polymer selected from the group set out in claim 16. Carrier characteristics are set out in claims 17-19. As such, those of ordinary skill would expect similar therapeutic effects on adhesions given the claims of US'546. The instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of US'546.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 19, 28, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (US Patent No. 7,056,591).

Pacetti et al discloses a polymer coating for a medical device (see Abstract). Polymers used for the coating are listed at col. 7, lines 65-67; col. 3, lines 1-32. Bioactives are listed at col. 9, lines 8-67. Pemirolast is found at col. 9, line 57. Therefore those of ordinary skill would have therefore found it well within their skill to coat a medical device with the claimed polymers used to deliver Pemirolast, with a reasonable expectation of anti-allergic results. The instant invention would have therefore been obvious to the of ordinary skill in the art at the time of invention given the teachings of US'591 to form a polymer coating comprising Pemirolast.

Response to Arguments

Applicant's arguments filed 04/15/2010 have been fully considered but they are not persuasive.

Applicant's argue that the provisional obviousness-type double patenting rejection is the only rejection left in the case and should be withdrawn. However, it is not the only rejection in the application (the rejection under 35 USC 103(a) will be discussed after this), and is therefore maintained in this action.

With regard to the rejection under 35 USC 103(a), applicant argues that Pacetti et al fail to disclose a composition or delivery vehicle suitable for local , non-systemic administration of a drug to a body and directly to tissue within a body cavity as claimed herein. However, the drug delivery coating is used for just that—local, non-systemic delivery. As for the delivery vehicle itself, osmotic pumps clearly fall within this category as well.

So that upon consideration, those of ordinary skill would have found it well within their skill to administer the device of Pacetti et al with a reasonable expectation of similar therapeutic results.

Applicant argues that the method of forming the implant devices of Pacetti et al would not allow for spraying directly on to injured tissues because they are toxic. However, applicant is not claiming a method of forming, but a composition. Spraying the coating directly on to tissue is not necessary . The claims read on a composition which are administered locally. The coating of the Pacetti et al device would provide for local delivery directly to the surrounding tissues and meets this criteria.

As for the selection of Pemirolast among other bioactive compounds, those of ordinary skill would have used the teachings of Pacetti et al to administer any number of bioactives in order to obtain the desired therapeutic result. Selection of Pemirolast is well within that suggestion by Pacetti et al. Intended use of the Pemirolast compound is not given patentable weight, since applicant is claiming a composition, not a method. Therefore, selection of Pemirolast is within the scope of the Pacetti et al disclosure, and those of ordinary skill would have found it well within their skill to select it. Applicant also does not set out amounts of Pemirolast which would be outside those disclosed by Pacetti et al.

Simply because Pacetti et al is silent to prevention of adhesion does not disqualify it as a reference under 35 USC 103(a). The composition is viewed a shaving a heretofore unknown property. However, the use of pemirolast in a local drug delivery system is well known as taught by Pacetti et al.

As for the term "single dose". A coating is considered a "single dose" formulation, and meets the parameters of claim 31.

As such, the rejection under 35 USC 103(a) is also maintained in this action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1617

Carlos A. Azpuru
Primary Examiner
Art Unit 1617

caz